



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum


Date: 12-16-02
From: Gloria Chang, IDS/Pharmacist, Division of Standards and Labeling Regulations,
Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820
Subject: 75-Day Premarket Notification of New Dietary Ingredients
To: Dockets Management Branch, HFA-305

New Dietary Ingredient: Astaxanthin (Extract of *Haematococcus pluvalis*)

Firm: Submitter: Ullman, Shapiro, and Ullman, LLP
Manufacturer: Mico Gaia, Inc.

Date Received by FDA: 3/07/02
90-Day Date: 6/05/02

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 **after 6/05/02. Hence, it can be displayed now.** Thank you for your assistance.


Gloria Chang, IDS/Pharmacist

Attachments

95S-0316

RPT/119



MAY 21 2002

Marc S. Ullman, Counselor at Law
Ullman, Shapiro & Ullman, LLP
299 Broadway, Suite 1700
New York, NY 10007

Dear Mr. Ullman:

This is in response to your letter to the Food and Drug Administration (FDA) dated January 9, 2002 and originally filed with FDA on January 15, 2002. Your notification concerns the new dietary ingredient, astaxanthin extracted from *Haematococcus pluvialis* algae and manufactured by Micro Gaia Inc. of Maui, Hawaii. In a subsequent telephone conversation on January 24, 2002 with you, Mr. Gary Coody of my staff informed you that the notification did not meet the minimum requirements of 21 CFR § 190.6. Mr. Coody stated that the 75 day safety review would not commence until the requested information was submitted and that the date that we received the information would be the new filing date. Your amended notification dated March 01, 2002 containing the additional information was received by FDA on March 07, 2002 and is the new effective filing date.

The law at 21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing it is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary supplement containing it is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your notification that you relied upon to conclude that astaxanthin extracted from the *Haematococcus pluvialis* algae and consumed in the recommended dose of 1 to 2 mg per day will reasonably be expected to be safe. Your notification notes that there were no age limitations or limitations on duration of use. Your notification states that the product will contain a warning that pregnant and lactating women should consult a physician before use. Because you did not include any long-term human toxicity studies in your notification, and there was no safety data on long term or chronic use in children and infants, we strongly suggest that you consider excluding use in this vulnerable subpopulation.

Further, to deter excessive intake, for example from other sources of the carotenoids either from foods or other dietary supplements, it may be helpful to advise all consumers not to exceed the recommended daily dose of astaxanthin.

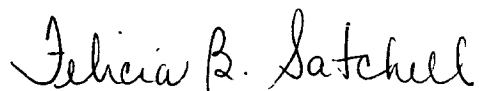
Although we are not finding at this time that the basis on which you have concluded that a dietary supplement containing astaxanthin will reasonably be expected to be safe is inadequate, FDA is not precluded from taking action in the future against a dietary supplement containing astaxanthin if it is found to be adulterated or misbranded. It is the manufacturer's or distributor's responsibility to ensure that any dietary ingredient contained in a dietary supplement is safe and properly labeled. Importantly, new dietary ingredients for use in dietary supplements that FDA has reviewed through the premarket notification process are not "approved" or "authorized" by the agency.

Your notification will be kept confidential for 90 days from the date of its receipt. After June 5, 2002, your notification will be placed on public display at FDA's Dockets Management Branch in docket number 95S-0316. However, any trade secret or otherwise confidential commercial information in the notification will not be disclosed to the public.

Prior to June 5, 2002, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Please contact us at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

A handwritten signature in cursive script that reads "Felicia B. Satchell".

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition